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EXAMINER
ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,639	MONTGOMERY, ALAN BRUCE	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-15 and 21-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15 and 21-33* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/06 & 3/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 12-15 and 21-33 are pending.

Election/Restrictions

Applicant's election with traverse of Group III (claims 12-15) in the reply filed on December 7, 2005 is acknowledged. The traversal is on the ground(s) that (a) the method of treatment of Group I is drawn to pulmonary infections only caused by gram-negative bacteria; (b) Group II should be examined with Group I, because the infections treated by the methods of Group I can only be affected successfully using aztreonam lysinate; (c) the compositions of Group III are required for the successful use of the methods of Group I and both groups I and II have the same class (514) and subclass (562); Group IV should not be restricted, because it is also classified in class 514, subclass 562. This traversal is moot, due to Applicant's cancellation of the non-elected claims.

The Examiner notes that the Applicant failed to address the generic species elections of a composition form (i.e. powders or aerosolizable solutions) and a specific gram-negative bacteria, originally stated in claims 1 and 3, respectively.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material

is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim 12 is objected to because of the following informalities: the Examiner believes the word "to" in line 7, should be replaced by the word "of". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 27 is a relative term, which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A person of ordinary skill in the art at the time of the instant invention would be unable to ascertain what Applicant considers the appropriate meaning of the phrase: "substantially free of an ethyl ester contaminant".

The term "reduced" in claim 28 is a relative term, which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A person of ordinary skill in the art would not be able to ascertain what Applicant considers a "reduced" quantity of beta lactams ring contaminant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-15 and 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al. (U.S. Patent No. 6,518,239) in view of Bastin, R. J. ("Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities" *Org. Proc. Res. & Develop.* 2000, *4*, 427-435).

The pending claims of the instant application are product-by-process claims and are therefore treated as compositions. Procedural steps, which have no effect on the make up of the composition, are given no weight in this examination (e.g. administration).

Kuo teaches highly dispersible formulations comprising an active agent and peptides, wherein the compositions exhibit superior aerosol properties and are preferred for **aerosolized administration to the lung** (i.e. inhalation) (abstract).

Kuo teaches that the dry powders of the invention are characterized by both **physical and chemical stability upon storage**. In one embodiment, the chemical stability of the dry powder is characterized by degradation of less than about 5% by weight of the active agent upon storage of the dry powdered composition under ambient conditions for a period of three months (col. 2, lines 42-51).

Kuo teaches highly desirable dry powder formulations comprising an active agent, wherein the preferred active agents include, for example, respiratory drugs (col. 6, line 29); **anti-infectives** (e.g. **antibiotics**) (col. 6, lines 34-35), **gram negative microorganism active agents** (e.g. ampicillin), **monbactams, such as aztreonam** (col. 7, lines 42-44), and the **acceptable salts** may include phosphate, **chloride**, lactate, stearate, etc. (col. 5, lines 23-33 and col. 7, lines

50-51). The active agent is delivered in **doses from about 0.001 mg/day to 100 mg/day** (col. 8, lines 5-13). The term "aztreonam" encompasses all forms of aztreonam such as the alpha and beta forms.

Kuo teaches that the therapeutically effective amount of active agent in the formulations will vary widely depending on the particular agent, its activity, the severity of the condition to be treated, the patient population, dosing requirements, and the desired therapeutic effect (col. 7, lines 64-67 and col. 8, lines 1-4).

Kuo teaches that more than one active agent may be incorporated into the formulations (col. 8, lines 15-17).

Example 1 (Tables 1-4) shows a pH range of from about 4.0 to about 10.0 and Kuo teaches the compositions may comprise a pH adjusting agent or a buffer (col. 10, lines 38-45). The formulations may be in a dry powder or **liquid form (i.e. solutions or colloidal suspensions)**. The active agent can be dissolved in a solvent (water, ethanol, ethanol-water, **saline**). The dry powder formulations can be made by lyophilization, **spray drying**, spray freeze-drying, etc. (col. 11, lines 2-19, col. 12, lines 23-26). The devices suitable for delivery of said formulations are discussed in columns 14-15. The said devices include **dry powder inhalers, metered dose inhalers, and nebulizers**. It is also disclosed that alternatively, the powders **may be dissolved** or suspended in a solvent such as **water**, ethanol, or **saline** and administered by nebulization (col. 15, lines 30-35).

Kuo lacks the teaching of a lysine salt form of aztreonam.

The teachings of Bastin have been set forth above.

The following reference, *Purification of Laboratory Chemicals (PLC), 4th Edn.*, Elsevier: **1996**, Chapter 1, is provided to demonstrate what was well known in the art regarding the physical purification of organic compounds.

PLC teaches that by suitable manipulation it is often possible to reduce the levels of impurities to acceptable limits, but absolute purity is an ideal, which, no matter how closely approached, can never be attained (page 1, 2nd to last sentence in the General Remarks section).

PLC teaches that if a solution contains extraneous colored material likely to contaminate the desired product, **this can often be removed by adding some activated charcoal** (decolorizing carbon) (page 12, 2nd section in the section entitled "Recrystallization").

PLC teaches that **filtration removes particulate impurities from liquids** and is also used to collect insoluble or crystalline solids, which separate or crystallize from solution (page 13, first sentences in the section entitled "Filtration").

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings Kuo and Bastin, because Kuo teaches formulations comprising aztreonam and its pharmaceutically acceptable salts. Kuo discloses an inhalable formulation comprising an active agent such as aztreonam, in either dry powder form or solution, where the dose is from 0.001 to 100 mg/day, wherein the solvent is water, ethanol, ethanol-water, or saline. Regarding claims 12-15 and 22-24, it would have been apparent to a skilled artisan that optimization of the amounts of the different components in a particular dosage form (e.g. an aqueous solution or dry powder) would be modified depending on the severity of the infection to be treated, the patient needing treatment, etc., as taught by Kuo. Furthermore, The amount of a specific ingredient in a composition is clearly a result effective parameter that a

person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Because the therapeutically effective amount of an active agent required is affected by the severity of the condition to be treated, the patient population, and the desired therapeutic effect, it would have been obvious to a skilled artisan to modify the dosing requirements in a given treatment to obtain the best therapeutic response in a subject treated with said compositions. Finally, a skilled artisan would have had a reasonable expectation of successfully combining the teachings of Kuo and Bastin, because Kuo teaches inhalable pharmaceutical formulations comprising active agents and/or pharmaceutically acceptable salts thereof, and Bastin teaches the motivation for using salts, with lysine salts given as an example of commonly employed amino acid salt forms. It would have been apparent to a skilled artisan that Kuo's dry powder formulations are stable, because Kuo reported a degradation of less than 5% in a period of three months.

Claims 12-15 and 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varia et al. (EP 0297580) in view of Bastin, R. J. ("Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities" *Org. Proc. Res. & Develop.* 2000, *4*, 427-435) and Akehurst (U.S. Patent No. 6,303,103).

The pending claims of the instant application are product-by-process claims and are therefore treated as compositions. Procedural steps, which have no effect on the make up of the composition, are given no weight in this examination (e.g. administration steps).

Varia teaches the preparation of the amorphous form of **alpha-** and beta- **aztreonam** and its **pharmaceutically acceptable salts**. The use of the amorphous aztreonam in pharmaceutical formulations results in products with **good stability** along with low particulate contamination (column 1, lines 10-19).

Varia teaches that freeze-dried or lyophilized L-arginine aztreonam salt for injection is prepared by mixing the required amount of alpha- or beta- aztreonam and 90% of the required L-arginine together (column 1, lines 28-31). An in-process **titration of alpha-aztreonam and L-arginine** is used to determine the amount of arginine required (see Examples 3-4).

Varia teaches that the pH is adjusted via the addition of L-arginine to a **pH value of 5.0**, and the resulting solution is **clarified and aseptically filtered** (column 1, lines 39-42). The resulting solution is transferred to the appropriate container and **freeze-dried by conventional methods (i.e. lyophilized).** The lyophilized product is **reconstituted in diluent**, using various volumes of diluent and quantities of aztreonam, depending on the intended use. Acceptable diluents are water, and others known to one skilled in the art (column 1, lines 47-56).

Varia teaches that other basic materials can be mixed with crystalline aztreonam to yield the desired lyophilized aztreonam salt product for reconstitution (column 2, lines 36-38).

Varia lacks the teaching of aztreonam lysinate (i.e. the lysine salt of aztreonam), alpha-aztreonam lysinate, and inhalable powders or aerosolizable solutions.

Bastin teaches that the selection of an appropriate salt form for a new chemical entity provides the pharmaceutical chemist and formulation scientist with the opportunity to modify the characteristics of the potential drug substance and to permit the development of dosage forms with good **bioavailability**, **stability**, manufacturability, and **patient compliance**. Salts are most commonly employed for **modifying aqueous solubility**, however the salt form will influence a range of other properties such as melting point, hygroscopicity, **chemical stability**, dissolution rate, **solution pH**, crystal form, and mechanical properties (abstract).

Bastin teaches that drug candidates are usually free bases, free acids, or neutral molecules, rather than their salts (page 427, right hand column, 1st paragraph).

Bastin teaches that for weakly basic drug substances, **salts of amino acids** (arginine or **lysine**), etc. could be considered (Table 1 and page 2nd paragraph, right hand column, both on page 428).

Akehurst teaches aerosol formulations for the administration of medicines by inhalation (abstract), which may contain a combination of two or more active ingredients. Aerosol compositions containing two active ingredients are known for the treatment of respiratory disorders. Acceptable medicaments for use in the Akehurst's formulations include, **anti-infectives**, including **penicillins (col. 3, line 46)**. Akehurst also teaches that it is clear to a person of skill in the art that medicaments may be used in the form of salts (e.g. alkali metal or amine salts or as acid additions salts) or as esters or solvates to optimize activity, and/or stability, and/or to minimize solubility of the medicament in the propellant (col. 3, lines 29-67).

The following reference, *Purification of Laboratory Chemicals (PLC), 4th Edn.*, Elsevier: **1996**, Chapter 1, is provided to demonstrate what was well known in the art regarding the physical purification of organic compounds.

PLC teaches that by suitable manipulation it is often possible to reduce the levels of impurities to acceptable limits, but absolute purity is an ideal, which, no matter how closely approached, can never be attained (page 1, 2nd to last sentence in the General Remarks section).

PLC teaches that if a solution contains extraneous colored material likely to contaminate the desired product, **this can often be removed by adding some activated charcoal** (decolorizing carbon) (page 12, 2nd section in the section entitled "Recrystallization").

PLC teaches that **filtration removes particulate impurities from liquids** and is also used to collect insoluble or crystalline solids, which separate or crystallize from solution (page 13, first sentences in the section entitled "Filtration").

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Varia, Bastin, and Akehurst, because Bastin teaches the development of salt forms of a candidate drug (influencing chemical stability, solubility, solution pH, etc), including the use of lysine salts, is commonly practiced in the art and Akehurst teaches medicinal aerosol formulations comprising anti-infectives for administration by inhalation. A skilled artisan would be motivated to use a lysine salt of alpha-aztreonam in lieu of the arginine and would have a reasonable expectation of success in the use of a lysine salt in lieu of an arginine salt, because lysine salts are known pharmaceutically acceptable salt forms of drug candidates (Bastin). The optimization of a composition's purity by the reduction of the amount of impurities present would have been obvious to a person of

ordinary skill in the art at the time of the instant invention. Routine optimization of an alpha-aztreonam lysinate composition would have yielded a composition having minimal amounts lower than 1%. It would have been apparent to a person of ordinary skill that a reduction of the levels of impurities would also enhance the stability of a composition. It would also have been obvious to a skilled artisan to make an inhalable composition, because aerosol formulations containing two medicaments are known for the treatment of respiratory disorders (Akehurst). The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 12-15, 21-25, and 29-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39-45 and 47 of copending Application No. 10/654,815 (copending '815) in view of Bastin et al. ("Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities" *Org. Proc. Res. & Develop.* 2000, *4*, 427-435).

Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims are overlapping in scope and/or have the same limitations. The intended uses suggested in claims 39-40 in copending '815 and in claims 14 and 19 of the instant application have been given no weight, because these are composition claims. Similarly, method steps in composition claims not affecting the composition (e.g. administration) have not been given any weight in the examination.

The claims of the instant application are drawn to alpha-aztreonam lysinate, whereas those of the copending application are drawn to aztreonam or a pharmaceutically acceptable salt thereof. The term aztreonam encompasses all the different forms of aztreonam (e.g. alpha, beta, delta, etc.).

Claims 41-46 of copending '815 are drawn to pharmaceutically acceptable salts selected from a Markush group that does not include lysinate.

Bastin et al. teaches that it is desirable to use salt forms of potential drug candidates, including, for example, salts formed from cationic amino acids such as lysine, arginine, and

histidine (abstract; 1st paragraph, right column, on page 427; Table 1 on page 428; and 2nd paragraph, right column, on page 428).

It would have been apparent to a person of ordinary skill at the time of the instant application that a lysinate salt of alpha-aztreonam is obvious over other pharmaceutically acceptable salt forms. A skilled artisan would have been motivated to use the teachings of copending '815 in view of the teachings of Bastion et al., because the use of salts of pharmaceutical actives is well known in the art. A skilled artisan would also have had a reasonable expectation of successfully using a salt of a known active agent per the art-accepted practices and knowledge regarding salts of drug candidates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12-15 and 21-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 14-17, 20 and 22 of copending Application No. 10/882,985 (copending '985). Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims are overlapping in scope and/or have the same limitations. Both claim sets in the instant application and copending '985 are drawn to compositions comprising powdered aztreonam lysinate, saline or other solutions of aztreonam lysinate, dosages of aztreonam lysinate in solution or powdered form

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni (Paddy) Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER